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| 10/672,077 | 09/29/2003 | Linda Arterburn | 62611.000235 | 4735 |

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HUNTON & WILLIAMS LLP
INTELLECTUAL PROPERTY DEPARTMENT
1900 K STREET, N.W.
SUITE 1200
WASHINGTON, DC 20006-1109

| EXAMINER | |
|---|---|
| KIM, JENNIFER M | |
| **ART UNIT** | **PAPER NUMBER** |
| 1617 | |

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

| Office Action Summary | Application No. | Applicant(s) | |
|---|---|---|---|
| | 10/672,077 | ARTERBURN ET AL. | |
| | Examiner | Art Unit | |
| | Jennifer Kim | 1617 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *23 April 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) *19* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18, 20-25* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16&,5/5/06,8/8&,4/29/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

## DETAILED ACTION

Applicants' election with traverse of Group I, claims 1-18 and 20-25 is acknowledged. The traversal is on the ground(s) that an undue search burden does not exist because a search of methods of improving glucose control as measured by glycosylated hemoglobin comprising administering DHA on a periodic basis would likely encompass subject matter pertaining to the treatment of individual at risk of developing metabolic syndrome by providing DHA. This is not found persuasive because the claims are drawn the different inventions having different etiologies involving different biological mechanisms of action involving different pathways, wherein metabolic syndrome is collection of abnormalities relating to decrease in HDL and increase in triglycerides while instant invention is relating to improving glucose control. Therefore, searches are not coextensive and there would be a serious burden on the examiner is restriction is not required. Accordingly, the requirement is still deemed proper and is therefore made FINAL.

Claims 1-18 and 20-25 are being examined only to the extent of Applicants' elected invention and claims19 is being withdrawn from consideration because they are non-elected invention.

### *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 2-4, 9 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Rubin (U.S.Patent No. 5,034,415) of record.

Rubin teaches that EPA and DHA mixtures are useful for treating diabetes mellitus. (claim 1). Rubin teaches the composition comprising DHA and EPA can replace butter and/or ordinary margarine or cooking oils. (column 5, lines 61-68).

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 5-8 and 20-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin (U.S. Patent No. 5,034,415) of record in view of Remmereit et al. (U.S.Patent No. 6,440,931 B1).

Rubin teaches that EPA and DHA mixtures are useful for treating diabetes mellitus. (claim 1). Rubin teaches the composition comprising DHA and EPA can replace butter and/or ordinary margarine or cooking oils. (column 5, lines 61-68). Rubin teaches that EPA and/or DHA composition can be administered at least 0.5gram, and preferably from 1.5 to 5 gram per day. (column 5, lines 25-30).

Rubin does not teach glycosylated hemoglobin (HbA1c) measurement in blood, combinations with the antidiabetic set forth in claim 5, prediabetic patients, chronic therapy, and amounts of DHA compared with other fatty acids set forth in claims 22-24.

Remmereit et al. teach that HbA1c (glycosylated hemoglobin) is a useful as an index of hyperglycemic stress, and is elevated in patients with poorly managed diabetes. Remmereit et al. teach that the glycation of HbA1c is a non-enzymatic, post-translational event linked to elevated levels of glucose in blood. Remmereit et al. teach that HbA1c levels may be determined as is known in the art by HPLC. (column 6, lines 34-42). Remmereit et al. teach that diabetes mellitus is a chronic metabolic disorder characterized by a high concentration of glucose in blood which is a result of insulin deficiency and/or insulin resistance. (column 1, lines 15-20). Remmereit et al. teach that insulin is the main form of treatment of Type I diabetes. Remmereit et al. teach that Type II diabetes can be treated with various oral anti-hyperglycemic agents like biguanidines (e.g., metformin), sulphonylurea compounds such as tolbutamide, chlorpropamide, glipizide and glibenclamide, and acarbose (i.e. an alpha-glucosidase inhibitor). (column 1, lines 24-36).

It would have been obvious to one of ordinary skill in the art to measure blood glucose level in diabetic patients of Rubin by measuring glycosylated hemoglobin (HbA1c) decrease because Rubin teaches that DHA composition is effective for treating diabetes and because Remmereit et al. teach HbA1c is elevated in patients with poorly managed diabetes and the determination of HbA1c level is well known in the art in view of Remmereit et al. One would have been motivated to measure decrease in HbA1c in

diabetic patients disclosed by Rubin in order to determine if the dosing adjustment of DHA/EPA composition in antidiabetic therapy is necessary. Further, it would have been obvious to one of ordinary skill in the art to combine other antidiabetic agents such as biguanidines (e.g., metformin), sulphonylurea compounds such as tolbutamide, chlorpropamide, glipizide and glibenclamide, and acarbose (i.e. an alpha-glucosidase inhibitor) to Rubin's composition in order to achieve at least an additive antidiabetic effect. The motivation for combining the components flows from their individually known common utility (see In re Kerkhoven, 205 USPQ 1069(CCPPA 1980)). It would have been obvious to one of ordinary skill in the art to employ Rubin's composition to treat diabetics chronically because that diabetes mellitus is a chronic disorder in view of Remmereit et al.

Claims 10-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rubin (U.S. Patent No. 5,034,415) of record in view of Remmereit et al. (U.S.Patent No. 6,440,931 B1) as applied to claims 1, 5-8 and 20-24 above, and further in view of Harris et al. (1997).

Rubin and Remmereit et al. as applied as before.

Rubin and Remmereit et al. do not teach the specific patient population set forth in claims 10-16 and dosing schedule set forth in claims 17 and 18.

Harris et al. teach that comparison of diabetes diagnostic categories in the U.S. Population including impaired fasting glucose defined as fasting plasma glucose of 110-

125mg/dl and mean HbA1c 7.07. (title, page 1859, right hand side, first paragraph, Table 2).

It would have been obvious to one of ordinary skill in the art to employ DHA/EPA composition taught by Rubin as modified by Remmereit et al. to a patient exhibiting fasting glucose between about 110 to about 125mg/dl and the criteria set forth in claims 10-18 because a fasting plasma glucose of 110-125mg/dl is defined as an impaired fasting glucose within the diagnostic classes taught by Harris et al. and because the criteria set forth in claims 10-16 are obvious the diagnostic categories within the teaching by Harris et al. and the variations within any one or more of the risk factors would be reasonable expected to be differ from patient to patient. Further, the dosing schedule or the frequency of administration of the antidiabetic to be used, the pharmaceutical forms, e.g., tablets, etc; mode of administration, flavors, surfactant are all deemed obvious since they are all within the knowledge of the skilled pharmacologist and represent conventional formulations and modes of administration. Thus, the claims fail to patentably distinguish over the state of the art as represented by the cited references.

None of the claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer Kim whose telephone number is 571-272-0628. The examiner can normally be reached on Monday through Friday 6:30 am to 3 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jennifer Kim
Patent Examiner
Art Unit 1617

Jmk
July 9, 2007